Proposed Decision Memo for Counseling to Prevent Tobacco Use (CAG-00420N)

Decision Summary

The Centers for Medicare and Medicaid Services (CMS) proposes the following:

The evidence is adequate to conclude that counseling to prevent tobacco use, which is recommended with a grade of A by the U.S. Preventive Services Task Force (USPSTF) for all adults and pregnant women who use tobacco, is reasonable and necessary for prevention of illness or disability and is appropriate for individuals entitled to benefits under Part A or enrolled under Part B.

Therefore CMS proposes to cover tobacco cessation counseling for outpatient and hospitalized Medicare beneficiaries:

- Who use tobacco, regardless of whether the patient has signs and symptoms of tobacco-related disease;
- Who are competent and alert at the time that counseling is provided; and
- Whose counseling is furnished by a qualified physician or other Medicare-recognized practitioner.

CMS proposes to cover two individual tobacco cessation counseling attempts per year. Each attempt may include a maximum of four intermediate or intensive sessions, with the total annual benefit thus covering up to eight sessions per Medicare beneficiary who uses tobacco. The practitioner and patient have the flexibility to choose between intermediate (more than three minutes) or intensive (more than ten minutes) cessation counseling sessions for each attempt.

This proposed decision does not modify existing coverage for minimal individual cessation counseling (three minutes or less), which is already covered as part of each Evaluation and Management (E&M) visit and is not separately billable.

We are requesting public comments on this proposed determination pursuant to Section 1862(l) of the Social Security Act. After considering the public comments, we will make a final determination and issue a final decision memorandum.

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Proposed Decision Memo

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SUBJECT:	Proposed Coverage Decision Memorandum for Counseling to Prevent Tobacco Use
DATE:	May 28, 2010

I. Decision

The Centers for Medicare and Medicaid Services (CMS) proposes the following:

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II. Background

Tobacco use remains the leading cause of preventable morbidity and mortality in the U.S. and is a major contributor to the nation's increasing medical costs.Despite the growing list of adverse health effects associated with smoking, more than 45 million U.S. adults continue to smoke and approximately 1200 die prematurely each day from tobacco-related diseases.Annual smoking-attributable expenditures can be measured both in direct medical costs ($96 billion) and in lost productivity ($97 billion), but the results of national surveys have raised concerns that recent declines in smoking prevalence among U.S. adults may have come to an end.[1]

According to the U.S. Department of Health and Human Services (DHHS) Public Health Service (PHS) Clinical Practice Guideline on Treating Tobacco Use and Dependence (2008), 4.5 million adults over 65 years of age smoke cigarettes.Even smokers over age 65, however, can benefit greatly from abstinence, and older smokers who quit can reduce their risk of death from coronary heart disease, chronic obstructive lung disease and lung cancer, as well as decrease their risk of osteoporosis.[2]

Medicare Part B (Section 210.4 of the NCD Manual) covers cessation counseling for individuals who use tobacco and have been diagnosed with a recognized tobacco-related disease or who exhibit symptoms consistent with tobacco-disease.[3]We are not reconsidering that NCD at this time.Rather, our current focus is on asymptomatic persons who smoke or use tobacco.

In November 2009, based upon authority to cover additional preventive services for Medicare beneficiaries, CMS initiated a new national coverage analysis to evaluate whether the existing evidence on counseling to prevent tobacco use is sufficient to extend national coverage for cessation counseling to those individuals who use tobacco but do not have signs or symptoms of tobacco-related disease.

Our analysis examines cessation counseling services furnished by qualified physicians and other Medicare-recognized practitioners, but does not address pharmacotherapy.Except for certain specific exceptions, the Medicare Part B program does not cover drugs and biologicals that are usually self-administered by the patient.[4]While some drugs may be covered under the separate Medicare Part D program, CMS does not issue national coverage determinations under Part D.

III. History of Medicare Coverage

Currently there is no Medicare coverage for counseling to prevent tobacco use in beneficiaries who do not already have a disease or an adverse health effect that has been found by the U.S. Surgeon General to be linked to tobacco use, or who are not taking a therapeutic agent whose metabolism or dosing is affected by tobacco use based on FDA-approved information.

Medicare Improvements for Patients and Providers Act (MIPPA) 2008

Effective January 1, 2009, in Section 101(a) of MIPPA (Public Law 110-275), CMS may add coverage of "additional preventive services" if certain statutory requirements are met.[5]Under our rules implementing this statute, 42 CFR 410.64, this benefit allows the coverage of preventive services not otherwise described in Title XVIII of the Act.[6]Specifically, this regulation provides:

§410.64 Additional preventive services

(a) Medicare Part B pays for additional preventive services not otherwise described in this subpart that identify medical conditions or risk factors for individuals if the Secretary determines through the national coverage determination process (as defined in section 1869(f)(1)(B) of the Act) that these services are all of the following:

(1) Reasonable and necessary for the prevention or early detection of illness or disability.
(2) Recommended with a grade of A or B by the United States Preventive Services Task Force.
(3) Appropriate for individuals entitled to benefits under part A or enrolled under Part B.

(b) In making determinations under paragraph (a) of this section regarding the coverage of a new preventive service, the Secretary may conduct an assessment of the relation between predicted outcomes and the expenditures for such services and may take into account the results of such an assessment in making such national coverage determinations.[7]

IV. Timeline of Recent Activities

November 30, 2009	CMS initiates this national coverage analysis for counseling to prevent tobacco use.
December 30, 2009	Initial 30-day public comment period closed.

V. FDA Status

FDA approval/clearance is not applicable to tobacco cessation counseling services.

VI. General Methodological Principles

When making national coverage determinations concerning additional preventive services, CMS applies the statutory criteria in §1861(ddd) of the Social Security Act and evaluates relevant clinical evidence to determine whether or not the service is reasonable and necessary for the prevention or early detection of illness or disability, is recommended with a grade of A or B by the USPSTF, and is appropriate for individuals entitled to benefits under part A or enrolled under Part B of the Medicare program.

Public comments sometimes cite published clinical evidence and give CMS useful information.Public comments that give information on unpublished evidence such as results of individual practitioners or patients are less rigorous and therefore less useful for making a coverage determination.Public comments that contain personal health information will not be made available to the public.CMS uses the initial public comments to inform its proposed decision.CMS responds in detail to the public comments on a proposed decision when issuing the final decision memorandum.

VII. Evidence

A.Introduction

As described in our original 2005 NCD for smoking and tobacco use cessation counseling (CAG-00241N), abstinence is the chief outcome measure in many studies of effectiveness of tobacco cessation counseling; and abstinence information is a substitute endpoint (surrogate) for clinical measures of improved health outcomes when evaluating the effectiveness of counseling.

Abstinence from tobacco use improves health outcomes, and effectiveness of tobacco cessation counseling is generally evaluated based on ability to bring about abstinence.Nonetheless, while permanent abstinence after quitting is the most desirable outcome, tobacco use/abuse is a chronic problem; and many patients eventually return to use (relapse). The term "relapse", however, is variably defined and problematic when comparing prolonged abstinence across multiple studies.

The U.S DHHS PHS Clinical Practice Guideline on "Treating Tobacco Use and Dependence: 2008 Update" provided a useful glossary containing the following definitions:

Abstinence percentage. The percentage of smokers who achieve long-term abstinence from smoking. The most frequently used abstinence measure for this Guideline was the percentage of smokers in a group or treatment condition who were abstinent at a follow-up point that occurred at least five months after treatment.

Continuous abstinence. A measure of tobacco abstinence based on whether subjects are continuously abstinent from smoking/tobacco use from their quit day to a designated outcome point (e.g., end of treatment, six months after the quit day).

Point prevalence. A measure of tobacco abstinence based on smoking/tobacco use occurrence within a set period (usually seven days), prior to a follow-up assessment.

Relapse. Return to regular smoking by someone who has quit. A distinction is sometimes made between "relapse" and a "lapse" (or a "slip"), which is a return to reduced smoking or brief smoking after quitting that falls short of a return to regular smoking.

Slip. A brief or reduced return to smoking after quitting. Also referred to as a "lapse".

Stepped-care. The practice of initiating treatment with a low-intensity intervention and then exposing treatment failures to successively more intense interventions.

Tobacco dependence. Dependence on any form of tobacco, including, but not exclusive to, cigarettes, pipes, cigars, and chewing tobacco.

Treatment. An action or program that aims to bring about identifiable outcomes. For tobacco dependence, the treatment generally is clinical in nature and may consist of counseling and the use of medications. Also may be referred to as "intervention."[8]

B.United States Preventive Services Task Force (USPSTF)

The USPSTF Reaffirmation Recommendation Statement on "Counseling and Interventions to Prevent Tobacco Use and Tobacco-Caused Disease in Adults and Pregnant Women" (April 2009) states the following:

- The USPSTF recommends that clinicians ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products. Grade: A recommendation.
- The USPSTF recommends that clinicians ask all pregnant women about tobacco use and provide augmented, pregnancy-tailored counseling for those who smoke.Grade: A recommendation.[9]

USPSTF Grade Definitions after May 2007:

What the Grades Mean and Suggestions for Practice

The U.S. Preventive Services Task Force (USPSTF) has updated its definitions of the grades it assigns to recommendations and now includes "suggestions for practice" associated with each grade.The USPSTF has also defined levels of certainty regarding net benefit.These definitions apply to USPSTF recommendations voted on after May 2007.

Grade	Definition	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C		

Grade	Definition	Suggestions for Practice
	The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is at least moderate certainty that the net benefit is small.	Offer or provide this service only if other considerations support the offering or providing the service in an individual patient.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the clinical considerations section of USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

Levels of Certainty Regarding Net Benefit

Level of Certainty*	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	

Level of Certainty*	Description
	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by such factors as: • The number, size, or quality of individual studies. • Inconsistency of findings across individual studies. • Limited generalizability of findings to routine primary care practice. • Lack of coherence in the chain of evidence. As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: • The limited number or size of studies. • Important flaws in study design or methods. • Inconsistency of findings across individual studies. • Gaps in the chain of evidence. • Findings not generalizable to routine primary care practice. • Lack of information on important health outcomes. More information may allow estimation of effects on health outcomes.

* The USPSTF defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.[10]

C.Literature Search

In addition to a prerequisite grade A or B USPSTF recommendation for the service, CMS must consider whether an additional preventive service is reasonable and necessary for the prevention or early detection of illness or disability, and whether the service is appropriate for individuals entitled to benefits under part A or enrolled under part B of the Medicare program.

To facilitate these determinations, we searched PubMed from 2005 to 2010 for original research studies, systematic reviews and clinical guidelines for smoking/tobacco cessation counseling and disparities in older or elderly adults as well as pregnant patients (to include disabled female Medicare beneficiaries < 65 years of age). Studies of cost and cost-effectiveness were also searched, as §1861(ddd)(2) expressly authorizes the agency to "conduct an assessment of the relation between predicted outcomes and the expenditures for such services".Studies must have been published in peer-reviewed English language journals, and abstracts were excluded.

Using these general parameters, CMS identified four new relevant research studies, five systematic reviews and two clinical guidelines.

D.Discussion of evidence reviewed

1.Evidence Questions

Our discussion focuses upon the adequacy of the evidence to draw conclusions about extending Medicare coverage for smoking cessation counseling to persons who use tobacco but do not have signs or symptoms of tobacco-related disease.CMS asks the following questions:

- *Is the evidence sufficient to determine that counseling to prevent tobacco use is recommended with a grade of A or B by the USPSTF for any indications?*
- *Is the evidence sufficient to determine that counseling to prevent tobacco use is reasonable and necessary for prevention of illness or disability in Medicare beneficiaries who use tobacco but do not have signs or symptoms of tobacco-related disease?*
- *Is the evidence sufficient to determine that counseling to prevent tobacco use is appropriate for Medicare beneficiaries who use tobacco but do not have signs or symptoms of tobacco-related disease?*

2.External technology assessments and systematic reviews

Interventions for Smoking Cessation in Hospitalised Patients (2007 Cochrane Review)

Since individuals may be more receptive to help at a time of perceived vulnerability, Rigotti and colleagues assessed effectiveness of smoking cessation interventions initiated for hospitalized patients. Selection criteria included randomized and quasi-randomized trials of behavioral, pharmacological or multicomponent smoking cessation interventions conducted with hospital patients who were current smokers or recent quitters (defined as having quit more than one month before admission). The intervention had to start in the hospital but could continue after hospital discharge, and the authors excluded any studies of patients admitted for psychiatric disorders or substance abuse, studies that did not report abstinence rates, and studies with follow-up of less than six months. Thirty-three (33) trials met inclusion criteria, and results showed that intensive counseling interventions – those that began during hospitalization and continued with supportive contacts for at least one month after discharge – increased smoking cessation rates after discharge [odds ratio (OR) 1.65, 95% confidence interval (CI) 1.44-1.90; 17 trials]. No statistically significant benefit was found for less intensive counseling interventions. One study that tested a single brief (≤15 minutes) in-hospital intervention was not effective (OR 1.16, 95% CI 0.80-1.67). Counseling of longer duration during the hospital stay was not associated with a higher quit rate (OR 1.08, 95% CI 0.89-1.29, eight trials), and counseling that began in hospital but had less than one month of supportive contact after discharge had no significant benefit (OR 1.09, 95% CI 0.91-1.31, six trials). Similar results were observed in smokers hospitalized due to cardiovascular disease, for whom intensive intervention with follow-up support increased odds of smoking cessation (OR 1.81, 95% CI 1.54-2.15, 11 trials), but less intensive interventions did not. Rigotti, *et al.* concluded high intensity behavioral interventions – those that began during a hospital stay and included at least one month of supportive contact after discharge – promoted tobacco cessation, and that such interventions were effective regardless of the patient's admitting diagnosis.[11]

Physician Advice for Smoking Cessation (2008 Cochrane Review)

Stead and colleagues searched the Cochrane Tobacco Addiction Group trials register to assess effectiveness of advice from physicians in promoting smoking cessation and compared minimal to more intensive physician interventions.Selection criteria included randomized trials of smoking cessation advice from medical practitioners in which abstinence was assessed at least six months after advice was first provided - where advice was defined as verbal instructions from the physician with a "stop smoking" message irrespective of whether or not information was provided about harmful effects of smoking.Studies that randomized patients to receive advice versus advice plus nicotine replacement therapy (NRT) were excluded, since those studies were said to be primarily comparisons of the effectiveness of NRT rather than advice.Studies where advice to stop smoking was included with multifactorial lifestyle counseling (including dietary and exercise advice) were also excluded.Trials with minimal intervention were defined as those where advice was provided (with or without a leaflet) during a single consultation lasting < 20 minutes, plus up to one follow-up visit; and trials with intensive intervention involved a greater time commitment at the initial consultation, use of materials other than leaflets (demonstration of expired carbon monoxide or pulmonary function tests, self-help manuals), or more than one follow-up visit.Forty-one (41) trials, conducted on > 31,000 smokers from 1972-2007, were identified.Some patients were at risk of specified diseases (chest disease, diabetes, ischemic heart disease), but most study participants were from unselected primary care populations. Subjects lost to follow-up were counted as smokers, and where possible, meta-analysis was performed using a Mantel-Haenszel fixed effect model.Results of pooled data from 17 trials of brief advice versus no advice (or usual care) showed a significant increase in the rate of quitting [relative risk (RR) 1.66, 95% CI 1.42-1.94]. In 11 trials where intervention was judged to be more intensive, the estimated effect was higher (RR 1.84, 95% CI 1.60-2.13), but there was no statistical difference between the intensive and minimal subgroups. Direct comparison of intensive versus minimal advice showed a small advantage of intensive advice (RR 1.37, 95% CI 1.20-1.56).Stead, *et al.* concluded that simple physician advice had a small effect on smoking cessation rates [assuming an unassisted quit rate of 2-3%, brief advice intervention can increase quitting by a further 1 to 3%], and that there was a small additional benefit of more intensive interventions compared to very brief interventions.[12]

Individual Behavioural Counselling for Smoking Cessation (2008 Cochrane Review)

Lancaster and Stead searched the Cochrane Tobacco Addiction Group Specialized Register for randomized or quasi-randomized trials with at least one treatment arm consisting of face-to-face individual counseling (more than 10 minutes) from a healthcare worker not involved in routine clinical care, i.e., excluding physicians, who are covered separately in Stead and colleagues' review (above) regarding specifically physician advice.The review also excluded interventions that addressed multiple risk factors in addition to smoking, as well as those interventions where counseling was confounded by provision of pharmacotherapy; and the primary outcome was smoking cessation at least six months after the start of counseling.Twenty-one (21) trials were identified (total patients > 7000 participants), including 18 trials that compared individual counseling to a minimal behavioral intervention and four trials that compared different types or intensities of counseling. Participants lost to follow up were assumed to be continuing smokers. For face-to-face individual counseling compared to minimal contact controls where the minimal intervention offered to the control group ranged from usual care to up to 10 minutes of advice, with or without self-help materials, the odds ratio (OR) for successful cessation was 1.56 (95% CI 1.32-1.84). There was, however, no greater effect of intensive counseling compared to brief counseling (OR 0.98, 95% CI 0.6-1.56).Lancaster and Stead concluded that individually delivered smoking cessation counseling could help people stop smoking.[13]

Interventions for Promoting Smoking Cessation during Pregnancy (2009 Cochrane Review)

Recognizing that smoking during pregnancy remains one of few preventable factors associated with complications of pregnancy, low birthweight, preterm birth and serious long-term health implications for women and babies, Lumley and colleagues systematically reviewed the effects of cessation interventions during pregnancy, generally given individually and including cognitive behaviour and motivational interviewing, on smoking behavior and perinatal health outcomes.Selection criteria included randomized controlled trials (RCTs) where smoking cessation during pregnancy was a primary aim of intervention.Trial authors were contacted to locate additional unpublished data, and subgroup analyses were conducted to assess risk of trial bias, intensity of intervention and main intervention strategy used.Seventy-two (72) trials were included, comprised of 56 RCTs (> 20,000 pregnant women) and nine cluster-randomised trials (> 5000 pregnant women) providing outcomes data.Results showed significant reduction in smoking in late pregnancy following interventions (RR 0.94, 95% CI 0.93-0.96], an absolute difference of six in 100 women who stopped smoking during pregnancy; but there was significant heterogeneity in the combined data (I^2> 60%). In trials with lowest risk of bias, interventions had less effect (RR 0.97, 95% CI 0.94-0.99) and lower heterogeneity (I^2= 36%); and eight trials of relapse prevention (> 1000 women) showed no statistically significant relapse reduction.Interventions reduced low birthweight (RR 0.83, 95% CI 0.73-0.95) and preterm birth (RR 0.86, 95% CI 0.74-0.98), and there was a 53.91gram (95% CI 10.44-95.38) increase in mean birthweight. Lumley, *et al.* concluded that smoking cessation interventions in pregnancy reduced the proportion of women who continue to smoke in late pregnancy, and also reduced low birthweight and preterm birth.[14]

Group Behaviour Therapy Programmes for Smoking Cessation (2009 Cochrane Review)

In 2009, Stead and Lancaster published an updated, edited version of its 2005 review of the effects of smoking cessation programs delivered in a group therapy format.Selection criteria included randomized trials that compared group therapy with self help, individual counseling, another intervention or no intervention (including usual care or a waiting list control), as well as trials that compared more than one group program.Relapse prevention studies, now covered in another review, were removed.The current review (up-to-date October 8, 2008) included trials with two or more group meetings reporting at least six months follow-up of smoking status, and the review excluded trials in which group therapy was provided to both the active therapy and placebo arms of trials of pharmacotherapies unless such trials had a factorial design. The primary outcome measure was abstinence from smoking after at least six months follow-up in patients who were smoking at baseline.Subjects lost to follow-up were analyzed as continuing smokers; and where possible, meta-analysis was performed using a fixed-effects (Mantel-Haenszel) model.Fifty-three trials met inclusion criteria for one or more comparisons in this review.In 13 trials comparing group program with self-help programs, results showed an increase in smoking cessation with use of a group program (N= 4375, RR 1.98, 95% CI 1.60 to 2.46).In eight trials comparing group therapy with controls offered no intervention, moderate to high statistical heterogeneity (I^2= 60%) between the trials precluded estimation of effect size and did not provide evidence for a specific benefit from group therapy. Results from five studies provided no evidence that group therapy was more effective than individual counseling, whether or not the number of sessions was matched; and there was a lack of evidence that meeting with a group of other smokers was a critical element in intensive smoking cessation programs.There was also limited evidence that addition of group therapy to other forms of treatment (such as advice from a health professional or nicotine replacement) produced extra benefit.Despite the risk of bias in the included studies and that most trials gave insufficient detail to be sure that randomization was effective, Stead and Lancaster concluded that group therapy was better for helping people stop smoking than self help and other less intensive interventions.There was, however, insufficient evidence to evaluate whether groups were more effective, or cost-effective, compared to intensive individual counseling; and there was not enough evidence to support the use of particular psychological components in a group therapy program .[15]

3.Internal technology assessment

Solberg, et al. (2006)

Solberg and colleagues updated 2001 estimates of the disease burden prevented and the cost effectiveness of tobacco-use screening and brief (less than three minutes) tobacco cessation counseling interventions relative to that of other clinical preventive services.The authors also evaluated repeated tobacco cessation counseling, because the existing literature had focused on single episodes of treatment.Literature searches (limited to counseling interventions which could be conducted and tested in primary care practices) revealed four models for calculating clinically preventable burden of deaths and morbidity from smoking, as well as the cost effectiveness of providing the service annually over time.To facilitate comparison of study results with existing estimates, all four alternative models were estimated.Model 1 analyzed one-time counseling and excluded savings from illness prevented, which is the model most comparable to the existing literature.Model 2 incorporated savings from prevented smoking-attributable illness into Model 1.Model 3 estimated repeated annual counseling without savings.Model 4 (the base-case model for ranking of preventive services) analyzed annual counseling and incorporated savings from prevented tobacco-associated illness.Results of Models 1 and 2, incorporating the effectiveness of one-time counseling, estimated a clinically preventable burden of 190,000 quality-adjusted life years (QALYs) saved at a cost of $1100 per QALY saved.Those estimates excluded savings from smoking-attributable disease prevented and used the average 12-month quit rate in clinical practice for tobacco screening plus brief cessation counseling with cessation medications (5.0%) and without such medications (2.4%). Including the savings of prevented smoking-attributable disease and using the effectiveness of repeated interventions over the lifetime of smokers (23.1%), 2.47 million QALYs were saved at a cost savings of $500 per smoker who received repeated cessation counseling – a large enough health impact to be among the most important evidence-based preventive services.Solberg, *et al.* concluded that repeated clinical tobacco-cessation counseling was one of the most cost-effective preventive services that can be provided in medical practice, and that greater efforts are needed to achieve more of this potential value by increasing current low levels of repeated counseling.[16]

Steinberg, et al. (2006)

Steinberg and colleagues analyzed more than 58,000 physician-patient ambulatory encounters from the National Ambulatory Medical Care Survey (NAMCS) 2001 and 2002, including patient demographics, diagnoses, tobacco counseling and prescriptions.Results showed that tobacco-use status was identified in 69% of patient encounters, with 16% of encounters indicating current use. Tobacco cessation counseling occurred in 22.5% of visits by tobacco users, and 2.4% of tobacco users were prescribed cessation medications, similar to analyses performed in 1991. Patient characteristics associated with being more likely to receive cessation counseling included being a new rather than an established patient (OR 1.34, 95% CI 1.00-1.77) and having a tobacco-caused diagnosis (OR 2.71, 95% CI 1.95-3.78).While the odds of receiving tobacco cessation medications varied by both gender and age – females less likely to receive medications (OR 0.45) and patients ≥ 65 years of age much less likely (OR 0.14) – the authors found no significant differences recorded by gender, age, race/ethnicity, practice location, or expected source of payment coverage for tobacco cessation counseling. Steinberg, *et al.* concluded that identification of tobacco status, cessation counseling rates and the use of cessation medications by physicians has remained low and unchanged from 1991.[17]

McCullough, et al. (2009)

McCullough and colleagues evaluated the impact of adding the following two smoking-related vital sign questions in an electronic medical records system on identification, assessment and counseling for patients who smoke: "Current smoker?" and "Plan to quit?"Baseline data and data after intervention were collected through record review of 899 randomly selected patient visits across three outpatient clinics. From before to after intervention, results showed that identification of smokers increased 18% (from 71% to 84%; P< 0.001), and assessment for a plan to quit increased 100% (from 25.5% to 51%; P< 0.005). Among all smokers, cessation counseling increased 26% (from 23.6% to 29.8%; P= 0.41), and significantly more smokers who received the assessment for a plan to quit received cessation counseling (46% versus 14%, P< 0.001). Regression analysis showed patients receiving an assessment for plan to quit were 80% more likely to receive cessation counseling (OR 0.209; 95% CI, 0.095-0.456).McCullough, *et al.* concluded that physician-documented cessation counseling rates were significantly higher when patients were asked two questions about smoking and were assessed for a plan to quit.[18]

Quinn, et al. (2009)

Recognizing that little was known about the effectiveness of the "5-As" model (Ask, Advise, Assess, Assist, and Arrange) outside the research setting, Quinn and colleagues analyzed the effectiveness of tobacco treatments in typical primary care practices. Subjects included current smokers enrolled in nine of ten, geographically diverse Health Maintenance Organizations (HMOs) participating the HMOs Investigating Tobacco (HIT) study.Smokers were surveyed at baseline (based upon questionnaires sent between September 1999 and August 2000) and at 12-month follow-up (65% response rate) to assess smoking status and tobacco treatments offered by clinicians and used by smokers.Analyses included the 80% of respondents (N= 2,325) who reported they had a visit with their clinician when they were smoking in the previous year, i.e., analyses based on reports from patients and which do not reflect the perspective of clinicians or notations from the medical record. Results showed that smokers were more often offered Advice (77%) than the more effective Assist treatments – cessation classes/counseling (41%) and pharmacotherapy (33%). One third of smokers reported using pharmacotherapy, but only 16% used cessation classes or counseling. At 12 month follow-up, 8.9% were abstinent for > 30 days. Compared with smokers who did not use cessation classes/counseling or pharmacotherapy, those who did use these services were more likely to quit (OR 1.82, CI 1.16-2.86 and OR 2.23, CI 1.56-3.20, respectively). Quinn, *et al.* concluded that smokers were more likely to report quitting (cessation twice as likely) when smokers attended cessation classes/received counseling or used pharmacotherapy.[19]

4.MEDCAC

No Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) was convened for this screening issue.

5.Clinical Guidelines

United States Preventive Services Task Force (USPSTF) 2009 *(see Section VII.B. above)*

The 2008 Guideline update's key recommendations, based on literature review and expert panel opinion, are as follows:

- Tobacco dependence is a chronic disease that often requires repeated intervention and multiple attempts to quit. Effective treatments exist, however, that can significantly increase rates of long-term abstinence.

- It is essential that clinicians and health care delivery systems consistently identify and document tobacco use status and treat every tobacco user seen in a health care setting.

- Tobacco dependence treatments are effective across a broad range of populations. Clinicians should encourage every patient willing to make a quit attempt to use the counseling treatments and medications recommended in the guideline.

- Brief tobacco dependence treatment is effective. Clinicians should offer every patient who uses tobacco at least the brief treatments shown to be effective in the guideline.

- Individual, group, and telephone counseling are effective, and their effectiveness increases with treatment intensity.Two components of counseling are especially effective, and clinicians should use these when counseling patients making a quit attempt: practical counseling (problem solving/skills training) and social support delivered as part of treatment.

- Numerous effective medications are available for tobacco dependence, and clinicians should encourage their use by all patients attempting to quit smoking – except when medically contraindicated or with specific populations for which there is insufficient evidence of effectiveness (i.e., pregnant women, smokeless tobacco users, light smokers, and adolescents).Seven first-line medications (five nicotine and two non-nicotine) reliably increase long-term smoking abstinence rates.Clinicians also should consider the use of certain combinations of medications identified as effective in the guideline.

- Counseling and medication are effective when used by themselves for treating tobacco dependence. The combination of counseling and medication, however, is more effective than either alone. Thus, clinicians should encourage all individuals making a quit attempt to use both counseling and medication.

- Telephone quitline counseling is effective with diverse populations and has broad reach. Therefore, clinicians and health care delivery systems should both ensure patient access to quitlines and promote quitline use.

- If a tobacco user currently is unwilling to make a quit attempt, clinicians should use the motivational treatments shown in this guideline to be effective in increasing future quit attempts.

- Tobacco dependence treatments are both clinically effective and highly cost-effective relative to interventions for other clinical disorders. Providing coverage for these treatments increases quit rates. Insurers and purchasers should ensure that all insurance plans include the counseling and medication identified as effective in the guideline as covered benefits.[20]

Numerous topics (characteristics and categories) of tobacco cessation interventions that were meta-analyzed for the 1996 and 2000 Guidelines – but not re-analyzed in the interim – are listed in Table 6.2 (page 75) of the 2008 Guideline update and include the following:

- Intensity of person-to-person clinical contact
  - No person-to-person intervention
  - Minimal counseling (longest session ≤ 3 minutes in duration)
  - Low intensity counseling (longest session > 3 minutes and ≤ 10 minutes in duration)
  - Higher intensity counseling (longest session > 10 minutes)
  - Total amount of contact time
  - Number of person-to-person treatment sessions

- Type of clinician
  - No clinician
  - Self-help materials only
  - Nonphysician health care clinician
  - Physician
  - Number of types of clinicians

- Formats of psychosocial intervention

- No contact
- Self-help/self-administered
- Individual counseling/contact
- Group counseling/contact
- Proactive telephone counseling/contact
- Number of types of formats

6.Public Comments

Public comment sometimes cites the published clinical evidence and gives CMS useful information. The CMS uses the initial public comments to inform its proposed decision. The CMS responds in detail to the public comments on a proposed decision when issuing the final decision memorandum.During the initial 30-day comment period (11/30/2009 – 12/30/2009), CMS received 12 timely comments, including one signed by seven different organizations, for a total of 18 commenters.

All commenters supported the expansion of Medicare coverage of tobacco cessation counseling to include all asymptomatic Medicare beneficiaries who use tobacco.Four commenters were providers or clinicians; six were training, education or advocacy groups; three were professional societies; three were academic and research organizations; one was a health insurer, and one did not identify a title or affiliation.

A number of commenters asked CMS to expand its analysis to include coverage of all FDA-approved prescription and over-the-counter medications demonstrated effective in helping individuals overcome their tobacco addiction.But another commenter noted that beneficiaries already have access to medications under the Medicare Part D drug program and suggested that expanding the tobacco cessation counseling benefit would encourage clinicians to both discuss tobacco use and prescribe pharmacologic treatments for asymptomatic individuals.

One commenter suggested there should be coverage for counseling and medications for at least two quit attempts per year, and another recommended coverage of multiple sessions of various types, including individual or group sessions of ten minutes or longer.

A single commenter supported expanded coverage of tobacco cessation counseling only if provided by a clinician in order to ensure appropriate education and needed intervention.But a number of other commenters recommended that CMS make payment to all healthcare providers for counseling services (including certain non-Medicare-recognized practitioners, such as tobacco treatment specialists and quitline providers) and that CMS eliminate or minimize copayments or deductibles for both cessation counseling and medications.

VIII. CMS Analysis

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act § 1869(f)(1)(B).In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage.Since January 1, 2009, CMS is authorized to cover "additional preventive services" (see Section III above) if certain statutory requirements are met as provided under §1861(ddd) of the Social Security Act and our regulations at 42 CFR 410.64:

(a) Medicare Part B pays for additional preventive services not otherwise described in this subpart that identify medical conditions or risk factors for individuals if the Secretary determines through the national coverage determination process (as defined in section 1869(f)(1)(B) of the Act) that these services are all of the following:

(1) Reasonable and necessary for the prevention or early detection of illness or disability.
(2) Recommended with a grade of A or B by the United States Preventive Services Task Force.
(3) Appropriate for individuals entitled to benefits under part A or enrolled under Part B.

(b) In making determinations under paragraph (a) of this section regarding the coverage of a new preventive service, the Secretary may conduct an assessment of the relation between predicted outcomes and the expenditures for such services and may take into account the results of such an assessment in making such national coverage determinations.[21]

United States Preventive Services Task Force (USPSTF)

Is the evidence sufficient to determine that counseling to prevent tobacco use is recommended with a grade of A or B by the USPSTF for any indications?

USPSTF Reaffirmation Recommendation Statement on "Counseling and Interventions to Prevent Tobacco Use and Tobacco-Caused Disease in Adults and Pregnant Women" (2009):

- The USPSTF recommends that clinicians ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products. Grade: A recommendation.
- The USPSTF recommends that clinicians ask all pregnant women about tobacco use and provide augmented, pregnancy-tailored counseling for those who smoke.Grade: A recommendation.[22]

According to the USPSTF statement, tobacco cessation interventions include behavioral counseling sessions.We therefore conclude that counseling to prevent tobacco use is recommended with a grade of A by the USPSTF for all adults and pregnant women who use tobacco.

Reasonable and Necessary for Prevention

Is the evidence sufficient to determine that counseling to prevent tobacco use is reasonable and necessary for prevention of illness or disability in Medicare beneficiaries who use tobacco but do not have signs or symptoms of tobacco-related disease?

Regarding the clinical effectiveness of interventions to change behavior, the USPSTF found convincing evidence in nonpregnant adults that smoking cessation interventions are effective in increasing the proportion of smokers who successfully quit and remain abstinent for one year.

The USPSTF also found convincing evidence that smoking cessation decreases the risk for heart disease, stroke and lung disease; and the USPSTF noted that tobacco cessation at any point during pregnancy yields substantial health benefits for the expectant mother and baby.

Lumley, *et al.* (Cochrane Review 2009) similarly concluded that tobacco cessation interventions in pregnancy reduced the proportion of women who continue to smoke in late pregnancy and reduced low birthweight and preterm birth.[23]No published studies were found that described harms of counseling to prevent tobacco use in adults or pregnant women.[24]

Solberg, *et al.'s* (2006) detailed study of the health impact and cost effectiveness of cessation counseling – part of the evidence base for the U.S. DHHS PHS 2008 Guideline recommendation (Strength of Evidence = A) for cost effectiveness of tobacco dependence interventions, including counseling – further concluded that repeated clinical tobacco-cessation counseling was one of the most cost-effective preventive services that can be provided in medical practice. [25],[26],[27]

After careful review of the available body of evidence, we conclude that counseling to prevent tobacco use is reasonable and necessary for prevention of illness or disability in all Medicare beneficiaries who use tobacco, whether they have signs or symptoms of tobacco-related disease or not.

Appropriateness

Is the evidence sufficient to determine that counseling to prevent tobacco use is appropriate for Medicare beneficiaries who use tobacco but do not have signs or symptoms of tobacco-related disease?

In a 2008 Cochrane Review that defined physician advice as verbal instructions with a "stop smoking" message irrespective of whether or not information was provided about the harmful effects of smoking, Stead, *et al.* concluded that (assuming an unassisted quit rate of 2-3%) brief physician advice can increase quitting by a further 1 to 3% and that a small additional benefit exists for more intensive compared to very brief interventions.[28]

McCullough, *et al.* (2009) reported that physician-documented tobacco cessation counseling rates were significantly higher when patients were asked two, simple, added vital sign questions about smoking and were assessed for a plan to quit: "Current smoker?" and "Plan to quit?".[29]Additionally, Quinn, *et al.* (2009) concluded that smokers were more likely to report quitting – cessation was twice as likely – when smokers attended cessation classes/received counseling.[30]

As described by the U.S. DHHS PHS 2008 Guideline in its specific subpopulations section on "Older Smokers", older age does not appear to diminish the desire to quit or the benefits of quitting smoking.In fact, smokers over the age of 65 can still benefit greatly from abstinence, including reducing their risk of death from coronary heart disease, chronic obstructive lung disease and lung cancer, as well as decreasing their risk of osteoporosis.

In a 2007 Cochrane Review, Rigotti, *et al.* also systematically evaluated cessation counseling in hospitalized patients and concluded that high intensity behavioral interventions (those which began during a hospital stay and included at least one month supportive contact after discharge) promoted smoking cessation, and that such interventions were effective regardless of the patient's admitting diagnosis.[31]

Regarding individual cessation counseling, Lancaster and Stead (2008) systematically reviewed 21 trials (totaling > 7000 participants), including 18 trials that compared individual counseling to minimal behavioral intervention and four trials that compared different types or intensities of counseling. For face-to-face individual counseling versus minimal contact controls – where the minimal intervention offered to the control comparison group ranged from usual care to up to 10 minutes of advice, with or without self-help materials – the odds ratio for successful cessation was 1.56 (95% CI 1.32-1.84).[32]Further, as stated in our response to public comments in the 2005 NCD (CAG-00241N) for tobacco cessation counseling – while the U.S. DHHS PHS 2000 Guideline concluded that group therapy was effective – an external (Rand Corporation, 2000) technology assessment concluded that individual cessation counseling appeared more effective than group therapy.

The U.S. DHHS PHS 2008 Guideline did not re-analyze or update its meta-analysis regarding the format type (delivery mode) of cessation counseling and cited no new peer-reviewed studies evaluating individual versus group counseling for older smokers.And a 2009 Cochrane Review of group therapy for tobacco cessation subsequently concluded that there is not enough evidence to evaluate whether group therapy programs are more effective, or cost-effective, compared to intensive individual counseling.[33]

Accordingly, the 2008 Guideline states the following three recommendations regarding the intensity of clinical interventions for all tobacco users:

- Recommendation:Minimal interventions lasting less than three minutes increase overall tobacco abstinence rates.Every tobacco user should be offered at least a minimal intervention, whether or not he or she is referred to an intensive intervention.**(Strength of Evidence = A)**

- Recommendation:There is a strong dose-response relation between the session length of person-to-person contact and successful treatment outcomes.Intensive interventions are more effective than less intensive interventions and should be used whenever possible.**(Strength of Evidence = A)**

- Recommendation:Person-to-person treatment delivered for four or more sessions appears especially effective in increasing abstinence rates.Therefore, if feasible, clinicians should strive to meet four or more times with individuals quitting tobacco use.**(Strength of Evidence = A)** [34]

After careful review of the available body of evidence, we conclude that individual counseling to prevent tobacco use is appropriate for prevention of illness or disability for all Medicare beneficiaries who use tobacco, whether they have signs or symptoms of tobacco-related disease or not, and that evidence necessary to support coverage of group therapy programs for Medicare beneficiaries remains lacking.

Disparities in Counseling for Smoking Cessation

In 2006, Steinberg and colleagues reported on the frequency and predictors of tobacco cessation counseling during office visits of tobacco users gathered during 58,057 physician-patient encounters recorded by the National Ambulatory Medical Care Survey (NAMCS) and National Hospital Ambulatory Medical Care Survey (NHAMCS) public-use data files from 2001-2002.While characteristics associated with lower likelihood of receiving prescribed tobacco cessation medications included female gender plus age 65 and above, the researchers found no significant differences recorded by gender, age, race/ethnicity, practice location, or expected source of payment coverage for tobacco cessation counseling.[35]

To the contrary, the U.S. DHHS PHS Clinical Practice Guideline for "Treating Tobacco Use and Dependence: 2008 Update" reported that large proportions of some racial and ethnic groups lack adequate access to primary care, are more likely have low socioeconomic status (SES), harbor misconceptions about tobacco dependence treatments, and may be less likely to receive advice to stop smoking or use tobacco dependence treatment.The 2008 Guideline update additionally noted that racial and ethnic minority groups differ from whites regarding both awareness of adverse health effects of smoking and benefits of proven treatments.Nevertheless, while smokers in several racial and ethnic groups attempt to quit as or more often than nonminority smokers, the guideline stated that such groups use effective treatments less often and have lower success rates.[36]

Regarding socioeconomic status (SES), the Guideline update emphasized that: 1) individuals with low SES and/or limited formal education, including the homeless, bear a disproportionate burden from tobacco; and 2) addressing this particular disparity is important to improve the overall health of the American public.According to the 2008 Guideline, such patients are more likely to smoke, to have limited access to effective treatment, to be misinformed about tobacco cessation medications, to be exposed to more permissive environmental and workplace smoking policies, and to be targeted by tobacco companies.[37]

CMS believes that coverage of individual counseling to prevent tobacco use will not only prevent illness or disability but will reduce disparities by providing access to tobacco cessation counseling for Medicare beneficiaries regardless of their gender, age, race, gender, ethnicity or socioeconomic status.

Summary

Having carefully evaluated newly published articles, reviews and guidelines, CMS believes there is adequate evidence that counseling to prevent tobacco use, which is recommended with a grade of A by the USPSTF for all adults and pregnant women who use tobacco, is reasonable and necessary for prevention of illness or disability and is appropriate for Medicare beneficiaries.

The USPSTF Reaffirmation Recommendation Statement (2009) does not address individual versus group counseling as a format type or delivery mode in its recommendations, and CMS continues to believe that individual cessation counseling (rather than group therapy) is more effective and appropriate for Medicare beneficiaries.

IX. Conclusion

The Centers for Medicare and Medicaid Services (CMS) proposes the following:

The evidence is adequate to conclude that counseling to prevent tobacco use, which is recommended with a grade of A by the U.S. Preventive Services Task Force (USPSTF) for all adults and pregnant women who use tobacco, is reasonable and necessary for prevention of illness or disability and is appropriate for individuals entitled to benefits under Part A or enrolled under Part B.

Therefore CMS proposes to cover tobacco cessation counseling for outpatient and hospitalized Medicare beneficiaries:

- Who use tobacco, regardless of whether the patient has signs and symptoms of tobacco-related disease;
- Who are competent and alert at the time that counseling is provided; and
- Whose counseling is furnished by a qualified physician or other Medicare-recognized practitioner.

CMS proposes to cover two individual tobacco cessation counseling attempts per year. Each attempt may include a maximum of four intermediate or intensive sessions, with the total annual benefit thus covering up to eight sessions per Medicare beneficiary who uses tobacco. The practitioner and patient have the flexibility to choose between intermediate (more than three minutes) or intensive (more than ten minutes) cessation counseling sessions for each attempt.

This proposed decision does not modify existing coverage for minimal individual cessation counseling (three minutes or less), which is already covered as part of each Evaluation and Management (E&M) visit and is not separately billable..

We are requesting public comments on this proposed determination pursuant to Section 1862(l) of the Social Security Act. After considering the public comments, we will make a final determination and issue a final decision memorandum.

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[1] Quinn, *et al.* (2007)

[2] http://www.surgeongeneral.gov/tobacco/treating_tobacco_use08.pdf(2008 PHS Guideline)

[3] http://www.cms.gov/Transmittals/Downloads/R36NCD.pdf(Section 210.4, Medicare NCD Manual)

[4] §1861(s)(2)(A) of the Social Security Act

[5] §1861(ddd) of the Social Security Act

[6] 73 FR 69726 and 69869 (November 19, 2008)

[7] 42 CFR 410.64

[8] http://www.surgeongeneral.gov/tobacco/treating_tobacco_use08.pdf

[9] http://www.ahrq.gov/clinic/uspstf09/tobacco/tobaccors2.htm(USPSTF, April 2009)

[10] http://www.ahrq.gov/clinic/uspstf/gradespost.htm#ast(USPSTF Grade Definitions After May 2007)

[11] Rigotti, *et al.*(2007)

[12] Stead, *et al.* (2008)

[13] Lancaster and Stead (2008)

[14] Lumley, *et al.* (2009)

[15] Stead and Lancaster (2009)

[16] Solberg, *et al.* (2006)

[17] Steinberg, *et al.* (2006)

[18] McCullough, *et al.* (2009)

[19] Quinn, *et al.* (2009)

[20] http://www.surgeongeneral.gov/tobacco/treating_tobacco_use08.pdf(DHHS PHS Guideline, May 2008)

[21] 42 CFR 410.64

[22] http://www.ahrq.gov/clinic/uspstf09/tobacco/tobaccors2.htm(USPSTF, April 2009)

[23] Lumley, *et al.* (2009)

[24] http://www.ahrq.gov/clinic/uspstf09/tobacco/tobaccors2.htm(USPSTF, April 2009)

[25] Recommendation: The tobacco dependence treatments shown to be effective in this Guideline (both counseling and medication) are highly cost-effective relative to other reimbursed treatments and should be provided to all smokers. (Strength of Evidence = A)(U.S. DHHS PHS 2008 Guideline, page 134-135)

[26] Solberg, *et al.* (2006)

[27] Although Solberg, *et al's.* (2006) evaluation regarding the cost-effectiveness of cessation counseling used quality-adjusted life years (QALYs), CMS does not have and is not establishing in this decision memorandum a coverage threshold for QALYs.

[28] Stead, *et al.* (2008)

[29] McCullough, *et al.* (2009)

[30] Quinn, *et al.* (2009)

[31] Rigotti, *et al.*(2007)

[32] Lancaster and Stead (2008)

[33] Stead and Lancaster (2009)

[34] The U.S. DHHS PHS Guideline Panel's three "**Strength of Evidence"** ratings are:**A.** Multiple well-designed randomized clinical trials, directly relevant to the recommendation, yielded a consistent pattern of findings.**B.** Some evidence from randomized clinical trials supported the recommendation, but the scientific support was not optimal. For instance, few randomized trials existed, the trials that did exist were somewhat inconsistent, or the trials were not directly relevant to the recommendation.**C.** Reserved for important clinical situations in which the Panel achieved consensus on the recommendation in the absence of relevant randomized controlled trials.

[35] Steinberg, *et al.* (2006)

[36] http://www.surgeongeneral.gov/tobacco/treating_tobacco_use08.pdf

[37] http://www.surgeongeneral.gov/tobacco/treating_tobacco_use08.pdf

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